CLAIMS

What is claimed is:

1. An isolated polynucleotide comprising nucleotides about 2028 to about 2239 of SEQ ID NO:1, wherein the polynucleotide exhibits urothelial cell-specific TRE activity.

2. The polynucleotide of claim 1, comprising nucleotides about 1647 to about 2239 of SEQ ID NO:1.

3. The polynucleotide of claim 1, comprising nucleotides about 1223 to about 2239 of SEQ ID NO:1.

4. The polynucleotide of claim 1, comprising nucleotides about 1 to about 2239 of SEQ ID NO:1.

5. The polynucleotide of claim 1 comprising nucleotides about 430 to about 2239 of SEQ ID NO:1.

6. An isolated polynucleotide comprising 200 contiguous nucleotides of SEQ ID NO:1, wherein the polynucleotide exhibits urothelial cell specific TRE activity.

7. The polynucleotide of claim 6, wherein the 200 contiguous nucleotides are within about 2028 to about 2239 of SEQ ID NO:1.

8. The polynucleotide of claim 6, wherein the 200 contiguous nucleotides are within about 1223 to about 2239 of SEQ ID NO:1.

9. The polynucleotide of claim 6, wherein the 200 contiguous nucleotides are within about 1647 to about 2239 of SEQ ID NO:1.

10. The polynucleotide of claim 6, wherein the 200 contiguous nucleotides are within about 430 to about 2239 of SEQ ID NO:1.

11. An isolated polynucleotide which hybridizes under stringent conditions to 200 contiguous nucleotides of SEQ ID NO:1 wherein the polynucleotide exhibits urothelial cell-specific TRE activity.

12. The isolated polynucleotide of claim 11, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within nucleotides about 2028 to about 2239 of SEQ ID NO:1.

13. The isolated polynucleotide of claim 11, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within nucleotides about 1647 to about 2239 of SEQ ID NO:1.

14. The isolated polynucleotide of claim 11, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within about 1223 to about 2239 of SEQ ID NO:1.

15. The isolated polynucleotide of claim 11, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within about 430-2239 of SEQ ID NO:1.

16. An isolated polynucleotide having at least about 70% sequence identity to 200 contiguous nucleotides of SEQ ID NO:1, wherein the polynucleotide exhibits urothelial cell-specific TRE activity.

17. The isolated polynucleotide of claim 16, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within nucleotides about 2028 to about 2239 of SEQ ID NO:1.

18. The isolated polynucleotide of claim 16, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within nucleotides about 1647 to about 2239 of SEQ ID NO:1.

19. The isolated polynucleotide of claim 16, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within nucleotides about 1223 to about 2239 of SEQ ID NO:1.

20. The isolated polynucleotide of claim 16, wherein the 200 contiguous nucleotides of SEQ ID NO:1 are within nucleotides about 430-2239 of SEQ ID NO:1.

21. The polynucleotide of claim 1 operably linked to a heterologous gene.

22. The polynucleotide of claim 6 operably linked to a heterologous gene.

23. A composition comprising the polynucleotide of claim 1 and a pharmaceutically acceptable excipient.

24. A composition comprising the polynucleotide of claim 1 and a buffer.

25. A composition comprising the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

26. A composition comprising the polynucleotide of claim 6 and a buffer.

27. A polynucleotide vector comprising a polynucleotide according to claim 1.

28. The vector according to claim 27, wherein the vector is a cloning vector.

29. The vector according to claim 27, wherein the vector is an expression vector.

30. The vector according to claim 27, wherein the vector is a viral vector.

31. The vector of claim 30 wherein said vector is an adenovirus vector.

32. The adenovirus vector of claim 31, wherein the isolated polynucleotide is operably linked to an adenovirus gene essential for adenoviral replication.

33. A polynucleotide vector comprising a polynucleotide according to claim 6.

34. The vector according to claim 33, wherein the vector is a cloning vector.

35. The vector according to claim 33, wherein the vector is an expression vector.

36. The vector according to claim 33, wherein the vector is a viral vector.

37. The vector of claim 36 wherein said vector is an adenovirus vector.

38. The adenovirus vector of claim 37, wherein the isolated polynucleotide is operably linked to an adenovirus gene essential for adenoviral replication.

39. An adenoviral vector comprising the polynucleotide of claim 1 operably linked to an adenovirus gene.

40. The adenoviral vector of claim 39, wherein the adenoviral gene is essential for replication.

41. The adenoviral vector of claim 40, wherein the gene essential for replication is an early gene.

42. The adenoviral vector of claim 39, wherein the adenoviral gene is ADP.

43. The adenoviral vector of claim 41, wherein the early gene is E1A.

44. The adenoviral vector of claim 41, wherein the early gene is E1B.

45. The adenoviral vector of claim 44, wherein E1B has a deletion of the 19-kDa region.

46. An adenoviral vector comprising a transgene operably linked to the polynucleotide of claim 1.

47. A host cell comprising the polynucleotide of claim 1.

48. A host cell comprising the vector of claim 27.

49. A host cell comprising the adenoviral vector of claim 39.

50. A host cell comprising the adenoviral vector of claim 46.

51. A method for increasing transcription of an operably linked polynucleotide sequence in a cell comprising introducing a polynucleotide of claim 1 operably linked to a sequence into a host cell which allows said urothelial cell-specific TRE to function, whereby transcription of the sequence is increased.

52. A method for expressing a polynucleotide coding sequence in a urothelial cell, said method comprising (a) introducing a vector comprising said coding sequence operably linked to a polynucleotide according to claim 1 into the urothelial cells; and expressing the coding sequence.

53. A method for screening for compounds which alter expression of a urothelial cell-specific gene, said method employing cells containing an expression construct, said expression construct comprising an *hUPII* TRE and a marker gene

whose expression provides a detectable signal, wherein said marker gene is under the transcriptional control of the *hUPII* TRE, and the cell allows function of the *hUPII* TRE, said method comprising (a) combining the cells with a candidate compound and incubating the cells for a sufficient time for detectable expression of the marker gene and (b) detecting the level of expression of the marker gene as compared to the level of expression in the absence of the compound, wherein an alteration of expression in the presence of the compound indicates that the compound alters urothelial cell-specific expression.

54. An adenovirus vector comprising a gene under transcriptional control of a urothelial cell-specific transcriptional response element (TRE).

55. An adenovirus vector according to claim 54, wherein the gene is an adenoviral gene.

56. An adenovirus vector according to claim 55, wherein the adenoviral gene is an adenoviral early gene.

57. An adenovirus vector according to claim 55, wherein the adenoviral gene is an adenoviral early gene essential for replication.

58. An adenovirus vector according to claim 57, wherein the adenoviral early gene is E1A.

59. An adenovirus vector according to claim 57, wherein the adenoviral early gene is E1B.

60. The adenovirus vector of claim 59, wherein E1B has a deletion of the 19-kDa region.

61. An adenovirus vector according to claim 54, wherein the adenoviral gene is an adenoviral late gene.

62. An adenovirus vector according to claim 54, wherein the TRE is derived from a uroplakin gene 5' flanking region.

63. An adenovirus vector according to claim 62, wherein the uroplakin gene 5' flanking region is derived from a mouse uroplakin II gene.

64. An adenovirus vector according to claim 63, wherein the TRE comprises nucleotides about -587 to about +1 of Fig. 2.

65. An adenovirus vector of claim 63, wherein the TRI comprising nucleotides about -965 to about +1 of Fig. 2.

66. An adenovirus vector according to claim 62, wherein the TRE is derived from a human uroplakin II gene.

67. An adenovirus vector according to claim 54, wherein said TRE comprises nucleotides 1-2239 of Fig. 1.

68. An adenovirus vector according to claim 54, wherein said TRE comprises nucleotides 2023-2239 of Fig. 1.

69. An adenovirus vector according to claim 54, wherein said TRE comprises nucleotides 430-2239 of Fig.1.

70. An adenovirus vector comprising

(a) an adenovirus gene under transcriptional control of a urothelial cell-specific transcriptional regulatory element (TRE); and

(b) an E3 region.

71. The adenovirus vector of claim 70, wherein the adenovirus gene is essential for replication.

72. The adenovirus vector of claim 71, wherein the adenovirus gene is an early gene.

73. The adenovirus vector of claim 72, wherein the early gene is E1A.

74. The adenovirus vector of claim 72, wherein the early gene is E1B.

75. The adenovirus vector of claim 74, wherein E1B has a deletion of the 19-kDa region.

76. The adenovirus vector of claim 72, wherein the early gene is E4.

77. The adenovirus vector according to claim 70, wherein the urothelial cell-specific TRE is derived from a uroplakin gene 5' flanking region.

78. The adenovirus vector according to claim 77, wherein the uroplakin gene 5' flanking region is derived from a mouse uroplakin II gene.

79. The adenovirus vector according to claim 77, wherein the uroplakin gene 5' flanking region is derived from a human uroplakin II gene.

80. A composition comprising the adenoviral vector of claim 54.

81. A composition comprising the adenoviral vector of claim 70.

82. A host cell comprising the adenoviral vector of claim 54.

83. A host cell comprising the adenoviral vector of claim 70.

84. A replication-competent adenovirus vector comprising co-transcribed first and second genes under transcriptional control of a urothelial cell-specific (TRE), wherein the second gene is under translational control of an internal ribosome entry site (IRES).

85. The adenovirus vector of claim 84 wherein said first gene is an adenovirus gene.

86. The adenovirus vector of claim 85 wherein said adenovirus gene is an early gene.

87. The adenovirus vector of claim 86 wherein said early gene is E3.

88. The adenovirus vector of claim 85 wherein said early gene is essential for viral replication.

89. The adenovirus vector of claim 88 wherein said early gene is E1A.

90. The adenovirus vector of claim 89 wherein E1A has a mutation of or deletion in its endogenous promoter.

91. The adenovirus vector of claim 88 wherein said early gene is E1B.

92. The adenovirus vector of claim 91 wherein E1B has a mutation of or deletion in its endogenous promoter.

93. The adenovirus vector of claim 91, wherein E1B has a deletion of the 19-kDa region.

94. The adenovirus vector of claim 85 wherein said adenovirus gene is E2.

95. The adenovirus vector of claim 85 wherein said adenovirus gene is E4.

96. A method of propagating an adenoviral vector targeted to urothelial cells, the method comprising combining an adenoviral vector of claim 54 with cells which allow the function of a urothelial cell-specific TRE, whereby said adenovirus vector is propagated.

97. A method of propagating an adenoviral vector targeted to urothelial cells, the method comprising combining an adenoviral vector of claim 70 with cells

which allow the function of a urothelial cell-specific TRE, whereby said adenovirus vector is propagated.

98. A method of detecting a urothelial cell in a sample, comprising contacting the sample with an adenoviral vector according to claim 54, whereby the adenovirus enters the cell.

99. A method for modifying the genotype of a urothelial cell comprising contacting the cell with the adenovirus vector according to claim 54 such that the adenovirus vector enters the cell.

100. A method for conferring selective cytotoxicity on a cell which allows a urothelial cell-specific TRE to function, comprising contacting said cell with an adenovirus vector of claim 54, wherein the adenovirus vector enters the cell.

101. A method for conferring selective cytotoxicity on a cell which allows a urothelial cell-specific TRE to function, comprising contacting said cell with an adenovirus vector of claim 84, wherein the adenovirus vector enters the cell.

102. A method for modifying the genotype of a urothelial cell, said method comprising contacting the urothelial cell with the adenoviral vector according to claim 54, wherein the vector enters the cell.

103. A method for propagating an adenovirus specific for cells which allow an urothelial cell-specific TRE to function, said method comprising combining an adenovirus vector of claim 84 with cells which allow function of an urothelial cell-specific TRE, whereby said adenovirus is propagated.